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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,517	09/16/2003	Sang Yup Lee	Q77445	2292
23373 7590 01/16/2007 SUGHRUE MION, PLLC	EXAMINER			
2100 PENNSYLVANIA AVENUE, N.W.			PROUTY, REBECCA E	
SUITE 800 WASHINGTO	N, DC 20037		ART UNIT	PAPER NUMBER
	•		1652	
			MAIL DATE	DELIVERY MODE
			01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
10/662,517	LEE ET AL.	
Examiner	Art Unit	
Rebecca E. Prouty	1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 26 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires 3 months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2: The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal ___. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. 🔲 The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: . (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 112, 1st enablement. 6. 🔲 Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. ⊠ For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) ⊠ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: 16. Claim(s) rejected: 1,2,4,6-9,11 and 15. Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. \times The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) 13. Other: ____.

> Rebecca E. Prouty **Primary Examiner** Art Unit: 1652

Application/Control Number: 10/662,517

Art Unit: 1652

The rejection of Claims 1, 2, 4, 6-9, 11 and 15 under 35 U.S.C. 103(a) over Ramirez et al. and Lamouse-Smith et al. in view of Martens et al., Swiss-Prot Accession No. P29460, Hatamoto et al. (JP 09/009982) and Koonin et al is maintained. Applicants arguments in response to this rejection are unclear and confusing and thus not persuasive. Applicants state that "Lamouse teaches that when an amino acid is present in a recombinant protein at levels significantly higher than that present in host cellular proteins, the amino acid becomes a limiting factor in expression level. In other words, an increase in specific amino acid level does not directly induce an increase in specific protein production; rather, the production of specific amino acid is inhibited by feedback inhibition regulatory network." However the second sentence is not a recapitulation of the first in different words as suggested by applicants but instead a complete change of the meaning of the first statement. As such it is not clear what applicants are arguing. Applicants argue that "If cysteine increases in host cellular protein, cellular regulating systems will inhibit cysteine production and IL-12 p40 serine-rich protein production will not increase". However, this is not persuasive as it misstates what would occur. A correct statement of what would be expected is "If the levels of free cysteine increases

Art Unit: 1652

intracellularly in the recombinant host, cellular regulating systems will inhibit cysteine production". However, in view of the disclosures of Lamouse-Smith et al. and Ramirez et al., a skilled artisan would not expect the levels of free cysteine to be high at all, as all available cysteine would be expected to be incorporated into recombinant protein. In other words the levels of free cysteine intracellularly in the recombinant host The remaining pages of applicants arguments would be low. discuss a variety of features of the present invention but their relevance to the instant rejection is not clear as the instant rejection suggested the construction of the claimed recombinant hosts and methods of using them for a different reason than that discussed by applicants. None of applicants discussion appears to address what the rejection suggests but only whether applicants reasons were obvious. As such the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval

Art Unit: 1652

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Rebecca Prouty

Primary Examiner Art Unit 1652